REMARKS

In the Office Action dated January 24, 2003, claims 14 and 60-77 in the above-identified U.S. patent application were rejected. Reconsideration of the rejections is respectfully requested in view of the above amendments and the following remarks.

The office action indicates that diagrams discussed during the November 29, 2002 interview were not submitted as requested by the Examiner. Attached are diagrams which show the differences between the claimed invention and the cited prior art. The office action also indicates that the applicants did not address the inconsistency regarding Herron '492 pointed out by the Examiner. The attached diagrams should clear up this issue. In addition, applicants point out that the third embodiment of Herron'492 requires activation of the silanized waveguide surface with glutardialdehyde in order to enable subsequent coupling of polyethylene glycol derivatized with ethylene diamine groups (PEG-ED2). Herron's surface coating would not otherwise be possible.

The office action indicates that claim 14 encompasses immobilization by any method including a PEG spacer. Applicants respectfully point out that immobilization with a preformed PEG antibody conjugate is not possible according to Herron's method as shown in the attached diagrams. The reaction of a PEG-ethylene diamine and an oxidized Fab' molecule would yield a polymeric crosslinked Fab'-PEG conjugate which can no longer be immobilized.

The office action points out a clerical error regarding the term "binding" in claims 64 and 65. Claims 64 and 65 have been amended correcting this error.

Claim 63 was rejected under 35 USC §112, first paragraph, as containing new matter regarding the term "preformed conjugate". Applicants point out examples 9 and 10 which

disclose the preparation (preformation) of the conjugates and their subsequent immobilization on the solid phase. Regarding support for claims 60-62 and 64-77, applicants point out page 4, lines 10-26, which discusses immobilization by direct absorptive binding, covalent coupling or coupling via high affinity binding pairs, lines 27-32, which discusses an alkylene blocker, page 5, lines 3-8, which discloses suitable blocking agents and binding of the blocker to the solid phase, page 3, lines 27-31, discusses suitable solid phases, and the examples discuss analyte specific regions immobilized on spatially limited test areas.

Claims 14 and 60-77 were rejected under 35 USC §112, first paragraph, as lacking support for the term "test reagent". Applicants point out that this term was changed to "detection reagents" in a prior response. Support for the language "detection reagents" can be found at page 11, lines 8-18 of the application regarding a modified soluble analyte specific reactant which is labeled and examples 13 and 14 in the application which use labeled reagents to detect the analyte. Applicants also point out that the term "test reagent" is disclosed on page 1, second paragraph, line 4.

Claims 60-67 were rejected under 35 USC §112, second paragraph, as indefinite, claims 60-67 have been amended to clarify the language found indefinite. In view of these amendments, applicants request that this rejection be withdrawn.

Claims 14 and 64 were rejected under 35 USC §102(b) as anticipated by Herron '492 or Herron '196. Claims 60-77 were rejected under 35 USC §103 as obvious over Herron '492 or Herron '196. Applicants respectfully point out that Herron attached the antibody to the solid surface using a PEG spacer but does not conjugate multiple PEG groups to the antibody to prevent non-specific interactions. Claim 14 currently requires a preformed conjugate to be applied to the solid phase which excludes Herron's process as a PEG spacer-antibody

conjugate is not possible due to intramolecular reactions. The disclosure cited in the office action (col. 16, lines 38-45 of Herron '196) clearly indicates that the PEG molecules were coupled to the silica surface (lines 38-40) and the other ethylenediamine group is later coupled to the antibody (lines 43-45). Herron '492 (col. 4, lines 2-5) indicates that the surface is coated with the derivatized PEG and later reacted with the Fab' capture molecules. Binding the PEG to the solid surface first, produces a different product than binding the PEG to the antibody first. In view of these differences, applicants request that this rejection be withdrawn.

Claims 14 and 64 were rejected under 35 USC §102(b) as anticipated by Caldwell '703 or Caldwell '503. Claims 60-77 were rejected under 35 USC §103(a) as unpatentable over Caldwell '703 or Caldwell '503. Caldwell '703 discloses a method where a derivatized Pluronic surfactant (a PPO/PEO copolymer) is adsorbed onto a hydrophobic surface. The entire hydrophobic surface is coated first and later, a biomolecule is immobilized on the pretreated solid surface via the surfactant (col. 9, lines 27-28). Thus, the polymeric surfactant is not conjugated to the antibody prior to immobilization on the solid surface, the polymeric surfactant is immobilized first in a process similar to Herron's. Caldwell '503 describes the coating of hydrophobic surfaces with a molecule referred to as end-group activated polymer (EGAP). Similar to Herron '492 the entire surface is coated with said EGAP. Subsequently, a biomolcule is covalently bound to the precoated surface. This procedure is discussed in several places in '503, col. 4, lines 50-55, column 6, lines 19-24 or example 2, col. 19, lines 7-25. Caldwell'503 clearly indicates in claim 1 that the copolymer is adsorbed to the hydrophobic surface prior to conjugation with a biomolecule. Thus, Caldwell '503 and '703 do not disclose a "preformed conjugate". In Caldwell '503 and '703 the solid phase is treated

to suppress unspecific binding to the solid phase. In contrast to this, in the present invention the reactant is treated and a conjugate is prepared which is subsequently coated as shown in the attached diagrams. In view of these differences, applicants request that this rejection be withdrawn.

Applicants respectfully submit that all of claims 14 and 60-77 are now in condition for allowance. If it is believed that the application is not in condition for allowance, it is respectfully requested that the undersigned attorney be contacted at the telephone number below.

In the event this paper is not considered to be timely filed, the Applicant respectfully petitions for an appropriate extension of time. Any fee for such an extension together with any additional fees that may be due with respect to this paper, may be charged to Counsel's Deposit Account No. 02-2135.

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Enclosures: Marked up copy of claims
Diagrams

Appendix 1

Marked up copy of claims to show amendments

60. (Amended) Method as claimed in claim 14, wherein ~~an analyte-specific modified solid phase reactant is used which is a conjugate with a partner of a high affinity binding pair~~ said analyte specific reactant is conjugated with a member of a high affinity binding pair.

61. (Amended) Method as claimed in claim 60, wherein ~~an analyte-specific modified solid phase reactant selected~~ said analyte-specific reactant is selected from analyte-specific antibodies, antigens, nucleic acids, nucleic acid analogues and lectins ~~is used~~.

64. (Amended) The method of claim 14, wherein the ~~solid phase~~ conjugate is immobilized by direct adsorptive binding or by covalent coupling or by coupling via high affinity ~~biding~~ binding pairs.

65. (Amended) The method of claim 14, wherein the ~~solid phase~~ conjugate is immobilized by coupling via high affinity ~~biding~~ binding pairs.

66. (Amended) The method of claim 14, wherein the solid phase is first coated with a first partner of a high affinity binding pair and then ~~a conjugate of the modified solid phase reactant with the second partner of the binding pair~~ said preformed conjugate is immobilized.

68. (Amended) The method of claim 14, wherein ~~the solid phase has immobilized thereon the~~ said preformed conjugate is a modified analyte specific solid phase reactant which is incubated with a further alkylene oxide modified ~~binding molecule~~ solid phase reactant which acts as a blocker.

69.(Amended) The method of claim 68, wherein ~~the blocker comprises non-analyte specific molecules~~ said further alkylene oxide modified solid phase reactant does not react

with said analyte.

73. (Amended) The method of claim 14, ~~wherein an alkylene oxide modified analyte specific reactant is in combination with an alkylene oxide modified blocker~~ further comprising applying an alkylene oxide modified blocker to said solid phase.

77.(Amended) The method of claim 14, wherein the solid phase comprises several test areas ~~containing different analyte-specific solid phase reactants~~ on which different preformed conjugates are immobilized.